

REMARKS

Following entry of the foregoing amendments, claims 1 to 26 and 30 to 42 will be pending in this patent application. Claims 1 to 19 have been withdrawn from consideration as drawn to non-elected subject matter. Claims 20, 21, 26, and 34 to 42 have been amended herein. Support for the amendments is found throughout the specification as originally filed, and the amendments therefore do not introduce new matter into the application.

Applicants respectfully request reconsideration of the rejections of record in view of the foregoing amendments and the following remarks.

Alleged Indefiniteness

Claims 22 and 24 have again been rejected under 35 U.S.C. § 112, second paragraph as indefinite because use of the term “modification” and the phrase “one or more D form amino acids,” allegedly renders the scope of these claims unclear. Applicants respectfully request reconsideration and withdrawal of this rejection because the meaning of the cited claim language would be readily apparent to those skilled in the art when the claims are considered in light of the state of the art and the description provided in the specification, and the identified language therefore does not render the scope of claims 22 and 24 unclear.

“The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification. If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 [second paragraph] demands no more.”¹ Definiteness of claim language must be analyzed, not in a vacuum, but in light of the content of the particular application disclosure, the teachings of the prior art, and the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.²

With respect to the Office’s objection to use of the term “modification” in claim 22, the Office asks “What modification? Where?”³ Applicants respectfully point out that claim 22 is a

¹ *Miles Laboratories, Inc. v. Shandon Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993).

² *In re Moore*, 439 F.2d 1232, 1235 (C.C.P.A. 1971).

³ Office action dated January 24, 2011, page 4.

Markush claim that lists the specific, possible modifications that can be made to the peptide recited in claim 20. Specifically, claim 22 recites that the peptide of claim 20 further comprises a modification selected from pegylation, biotinylation, acetylation, ubiquitination, amidation, a radiolabel, an Fc antibody, and one or more D form amino acids. Applicants thus do not understand the reasoning behind the Office's inquiry as to "What modification?" Moreover, the peptide modifications recited in claim 22 are well-known to those skilled in the art, and such artisans would fully understand how and where such modifications can be introduced into peptides, as evidenced by the abundant description of such modifications in the art, including the articles attached as Appendix A to the response to the previous official action that was issued for this application.⁴ Those skilled in the art would thus readily understand the meaning of the term "modification" as it is used in claim 22, and the term therefore would not render the metes and bounds of claim 22 unclear to those skilled in the art.

Regarding the Office's objection to the phrase "one or more D form amino acids" in claim 22, the Office questions whether substitution of D form amino acids for L form amino acids would affect the activity of the resulting, modified peptide and indicates that "Applicant may wish to consider filing a reference that supports that substituting a D amino acid substitution [*sic*] 'anywhere' in a peptide will maintain utility."⁵ Applicants respectfully point out that an extensive body of scientific literature exists that demonstrates that substitution of D form amino acids for L form amino acids in surface active peptides does not diminish the biological activity of the resulting modified peptides, and such modifications actually enhance the stability of the peptides. Exemplary publications providing experimental evidence of these effects are attached hereto as Appendix A.⁶ Skilled artisans would thus readily understand the meaning of the phrase "one or more D form amino acids" as it is used in claim 22 in view of the state of the art, and the

⁴ Kaiser, P., *et al.*, *Genome Biology*, 6, 2005, 233; Reubi, J.C., *et al.*, *J. Nuclear Med.*, 2005, 46, 67S; Lindegren, S., *et al.*, *Bioconjugate Chem.*, 2002, 13, 502; Brinckerhoff, L.H., *et al.*, *Int. J. Cancer*, 1999, 83, 326; Vaccaro, C., *et al.*, *Nature Biotech.*, 2005, 23, 1283; Na, D.H., *et al.*, *Pharm. Res.*, 2005, 22, 743; Werle, M., *et al.*, *Amino Acids*, 2006, 30, 351, attached as Appendix A to the response filed November 4, 2010.

⁵ Office action dated January 24, 2011, page 4.

⁶ Fassina, G., *et al.*, *J. Biol. Chem.*, 1989, 264, 11252; Bessalle, R., *et al.*, *FEBS*, 1990, 274, 151; Nomizu, M.N., *et al.*, *J. Biol. Chem.*, 1992, 267, 14118; Li, C., *et al.*, *Biochemistry*, 1997, 36, 15404; Miles, A.J., *et al.*, *J. Biol. Chem.*, 1994, 269, 30939; Zhou, N., *et al.*, *J. Biol. Chem.*, 2002, 277, 17476; and Wade, D., *et al.*, *Proc. Natl. Acad. Sci., USA*, 1990, 87, 4761, attached hereto as Appendix A.

DOCKET NO.: NIHA-0383
Application No.: 10/588,884
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PATENT

phrase would therefore not render the metes and bounds of claim 22 unclear to those skilled in the art.

The scope of the pending claims would thus be readily apparent to those skilled in the art, and the claims therefore meet the requirements of 35 U.S.C. § 112, second paragraph. Applicants accordingly, respectfully, request withdrawal of the rejection.

Alleged Failure to Meet the Written Description Requirement and Indefiniteness

Claims 20 to 26 and 30 to 42 have been rejected under 35 U.S.C. § 112, first and second paragraphs because recitation of the phrase “designated as” in claims 20, 21, 26, and 34 to 42 to refer to the sequence identification numbers assigned to particular amino acid sequences present in the sequence listing for this application is allegedly not supported by the application as originally filed and also allegedly renders the scope of the claims unclear. Without conceding the correctness of these assertions, and to advance prosecution, claims 20, 21, 26, and 34 to 42 have been amended herein to replace the phrase “designated as” with the term “of,” obviating the rejections in light of Examiner Audette’s indication that such an amendment would overcome the rejections in a teleconference with Applicants’ undersigned representative on February 28, 2011. Applicants accordingly, respectfully, request withdrawal of the rejections.

Conclusion

Applicants believe that the foregoing constitutes a complete and full response to the official action of record. An early and favorable action is therefore respectfully requested.

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Respectfully submitted,

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